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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,452	01/07/2002	David Wallach	WALLACH=1E	6011

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	4

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,452	WALLACH ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *3* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED OFFICE ACTION

Currently, claims 1-9 are pending and under consideration.

Formal Matters:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the elected claims are directed.

Double Patenting Rejections:

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 3-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 7-11, 14 and 15 of U.S. Patent No. 5,695,953. Although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons below. The present claims 1, 4, 6 and 8 are not patentably distinct from claims 1, 8, 10, and 14 of the US patent: claim 1 of the US patent is directed to a

recombinant DNA molecule comprising the nucleotide sequence coding for a naturally occurring soluble TNF inhibitory protein, with the sequence and functional limitations identical to that of claim 1 of the instant invention. The present claim 1 is directed to a recombinant DNA molecule comprising the nucleotide sequence encoding for the same protein although "naturally occurring" is not emphasized in the present claim 1. As the naturally occurring species would anticipate the instant claim, they are not patentably distinct from each other. Further, claims 8, 10, and 14 of the US patent are directed to a replicable expression vehicle, a host cell, and a process for producing said protein using the host cell, and they are dependent from claim 2, which depends from claim 1. The present claims 4, 6 and 8, depending from claim 1, are directed to an expression vector, a host cell, and a method of producing said protein using the host cell. As the independent claim 1 (claim 2 also, see below) of the patent is not patentably distinct from the independent claim 1 of the instant invention, and as the present claims 4, 6 and 8 are directed to the same subject matter as that of claims 8, 10, and 14 of the US patent, the present claims 4, 6 and 8 are not patentably distinct from claims 8, 10, and 14 of the US patent, even though claim 8 of the patent recites "a *replicable* expression vehicle", which is inherent to an expression vector.

The present claims 3, 5, 7 and 9 are not patentably distinct from claims 7, 9, 11, and 15 of the US patent for the same reasons above.

Claims 8 and 9 are also rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,811,261. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons: claim 1 of the US patent is directed to a method for the production of a soluble recombinant protein having the TNF binding characteristics of human TBP-I by generating and culturing transfected cells, and recovering the desired protein. The present claims 14 and 15 are directed to a recombinant method of producing a polypeptide capable of interacting with TNF, and they are not patentably distinct from claim 1 of the US patent because both are drawn to a recombinant method of producing a polypeptide having the same functional property as TNF binding (the patent) is "interacting with TNF" (the present claims). Although the present claims do not recite the step of transfecting mammalian cell, which is the way of

generating a host cell, however, as "a host cell" is used in the present method, the step of transfecting mammalian cell is inherently encompassed in the instant invention. As such, the present claims 8 and 9 are not patentably distinct from claim 1 of the US patent.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 2 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 5,695,953, as the genomic DNA or cDNA would inevitably encode the naturally occurring protein. This is a double patenting rejection.

Objections and Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is incomplete because it depends on itself.

Claims 8 and 9 are indefinite for failing to adequately point out what applicants see as the invention, as the host cell may produce polypeptides other than the polypeptide encoded by the

transformed or transfected expression vector. The claims should be amended to indicate the identity of the polypeptide being produced.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-9 are directed to a recombinant DNA molecule encoding a polypeptide comprising SEQ ID NO:1, fragments thereof, an expression vector comprising the DNA, a host cell thereof, and a recombinant method of producing the functional polypeptide, wherein the DNA molecule is genomic DNA or cDNA. However, the specification merely discloses a small portion of the polypeptide sequence, namely the N-terminal 16 amino acid residues, and no DNA sequence of any kind is identified or particularly described.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116).

With the exception of the DNA sequence encoding the N-terminal 16 amino acid residues of the polypeptide, the skilled artisan cannot envision the detailed chemical structure of the encompassed genomic DNA or cDNA encoding the polypeptide, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is

required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, no DNA except the fragment encoding the N-terminal 16 amino acid residues of the polypeptide meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Prior Art:

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Creasey et al. (Proc. Natl. Acad. Sci. USA, 1987, 84(10): 3293-7, provide by applicants) discloses that a hTNF receptor, having a high molecular weight and noncovalently linked membrane-bound polypeptides, is associated with cytotoxicity (the abstract).

Hass et al. (J. Biol. Chem., 1985, 260 (22): 12214, provide by applicants) discloses that hTNF-β binds to mouse fibroblasts and cause the ultimate cell lysis, and that neutralizing antibodies to hTNF-β efficiently inhibited the binding of hTNF-β to the cells (the abstract).

Seckinger et al. (J. Exp. Med., 1988, 167: 1511-16, provide by applicants) discloses a human inhibitor of TNF-α in urine with an apparent mol wt of 40-60 X 10(3) and a pI range of 5.5-6.1 (the abstract).

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 703-305-1345. The examiner can normally be reached on Monday - Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Lorraine Spector

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
11/18/03